

Remarks/Arguments

Claims 1-20 are pending in this Application. Claims 12-18 were withdrawn from further consideration pursuant to a provisional election by telephone of the invention of Group I, Claims 1-11 and 19-20, drawn to a method of treating cells undergoing uncontrolled growth. In the Office Action mailed on July 7, 2005, the Examiner:

1. requested affirmation of the provisional election of the invention of Group I;
2. objected to Claim 20 because of informalities;
3. rejected Claims 1-11 and 19-20 under 35 U.S.C. § 112, second paragraph, as being vague and indefinite;
4. rejected Claims 1 and 3-9 under 35 U.S.C. § 102(a) as being anticipated by Awasthi et al. (Proc. Am. Assoc. Cancer. Res. March 2002;43 Abstract #4717);
5. rejected Claims 1 and 3-9 under 35 U.S.C. § 102(b) as being anticipated by Awasthi et al. (Proc. Am. Assoc. Cancer. Res. March 2001;44 Abstract #1517);
6. rejected Claims 1-9 under 35 U.S.C. § 103(a) as being unpatentable over Awasthi et al., (2001) in combination with American Type Culture Collection (Tumor Cell Lines, 2001);
7. rejected Claims 1-11 under 35 U.S.C. § 103(a) as being unpatentable over Awasthi et al., (2001) in view of Sause WT (Chest, 1999; 116:504S-508S); and
8. rejected Claims 19-20 under 35 U.S.C. § 103(a) as being unpatentable over Chen et al. (US 2002/001956) in combination with Awasthi et al. (2001).

Applicants respectfully address the basis for each of the Examiner's objections and rejections below.

Restriction/Election

On page 4 of the Office Action, the Examiner requested that the provisional election of Group I, claims 1-11 and 19-20, be confirmed. Applicants herewith confirms such election and acknowledges withdrawal of the species election of claim 2. the claims be restricted to one four inventions. Claims 12-18 have been withdrawn from further prosecution; any claim cancellation will be made upon the filing of a divisional application.

Claim Objection

On page 4 of the Office Action, the Examiner objected to Claim 20 for depending from Claim 17. Applicants thank the Examiner for pointing this out, acknowledge the Examiner's interpretation of Claim 20 as depending from Claim 19, and have amended Claim 20 to provide proper antecedent basis. Entry and allowance of amended Claim 20 is respectfully requested.

Claim Rejections – 35 U.S.C. § 112, second paragraph

On page 4 of the Office Action, the Examiner rejected Claims 1-11 and 19-20 under 35 U.S.C. § 112, second paragraph, as being vague and indefinite. The Examiner states that the term RLIP76 does not appear to be the standard term used throughout all laboratories. Applicants respectfully amend independent Claims 1 and 19 to replace the term RLIP76 with the official name of the protein which is ralA binding protein1, as now identified by the National Center for Biotechnology, the US National Library of Medicine (e.g., see GenBank, Accession No. Q15311). In addition, Applicants respectfully request entry of amendments to the Specification as presented on page 2 of this paper in which paragraph [0033] is amended to provide the official genomic name and product produced therefrom. No new matter is included with such amendments. Applicants respectfully request entry and allowance of these amendments.

Claim Rejections – 35 U.S.C. § 102(a)

On page 6 of the Office Action, the Examiner rejected Claims 1 and 3-9 under 35 U.S.C. § 102(a) as being anticipated by Awasthi et al. (Proc. Am. Assoc. Cancer. Res. March 2002;43 Abstract #4717, herein "Awasthi 2002"). Applicants respectfully submit a Declaration under 37 § CFR 1.131. The Declaration is signed by the Applicants establishing that the Awasthi 2002 reference is describing Applicants' own work. Accordingly, Applicants submits that subject matter considered prior art under 35 U.S.C. § 102(a) is now disqualified as prior art against this Application for invention.

Claim Rejections – 35 U.S.C. § 102(b)

On page 6 of the Office Action, the Examiner rejected Claims 1 and 3-9 under 35 U.S.C. § 102(b) as being anticipated by Awasthi et al. (Proc. Am. Assoc. Cancer. Res. March 2001;44 Abstract #1517, herein "Awasthi 2001"). Applicants respectfully submit amended Claim 1, amended to include a method of "treating one or more cells undergoing uncontrolled growth

comprising the step of contacting one or more cells with an antibody to ralA binding protein1, wherein the direct contact is cytotoxic to the one or more cells in the absence of an additional agent.” [Emphasis indicating amended text] Applicant respectfully points out that Awasthi 2001 does not disclose or suggest contacting one or more cells with an antibody to ralA binding protein1 wherein the direct contact is cytotoxic to the one or more cells in the absence of an additional agent. Instead, Awasthi 2001 discloses that “antibodies markedly augment the cytotoxicity of doxorubicin,” but this is not equivalent to the antibodies themselves being cytotoxic. Many chemotherapeutic agents exhibit enhanced cytotoxicity when combined with a non-chemotherapeutic compound or agent, but the non-chemotherapeutic compound is not, itself, chemotherapeutic. For example, the antidepressant, amitriptyline, has been found to enhance cytotoxicity of other chemotherapy agents, but is not, itself, a chemotherapeutic agent. As such, Applicants submit that Awasthi 2001 does not teach each and every element of amended Claim 1. Claim 1 is, therefore, not anticipated by Awasthi 2001. Entry and allowance of amended Claim 1 and its dependents, Claims 3-9, are respectfully requested. Applicants also submit amended Claims 3 and 6, amended as to matters of form. No new matter has been introduced with these amendments. Their entry and allowance are respectfully requested.

Claim Rejections – 35 U.S.C. § 103(a)

On page 7 of the Office Action, the Examiner rejected Claims 1-9 under 35 U.S.C. § 103(a) as being unpatentable over Awasthi 2001 in combination with American Type Culture Collection (herein “ATCC”). For the reasons set forth above, Applicants submit that Claims 1-9 are not anticipated by Awasthi 2001. Combining Awasthi 2001 with ATCC, which is merely a collection of cell types, does not overcome the fundamental failure of Awasthi 2001 to anticipate each and every element of independent and amended Claim 1 or amended Claim 1 on its whole. ATCC does not suggest or teach contacting one or more cells with an antibody to ralA binding protein1 wherein the direct contact is cytotoxic to the one or more cells in the absence of an additional agent. Thus, combining ATCC with Awasthi 2001 does not overcome the deficiencies of Awasthi 2001 as described above nor do the combination teach Applicants claimed invention on its whole. With such differences in teachings between Awasthi 2001 and ATCC, no person of ordinary skill would have reason to combine such references to provide for Applicants’ invention as claimed in amended Claim 1. Moreover, there is no teaching or suggestion in Awasthi 2001

or in ATCC to modify or combine references in such a way that would resemble Applicants' invention as claimed in amended Claim 1; nor is there any indication of a reasonable expectation of success if such references were to be combined. Accordingly, Applicants submit that amended Claim 1 and its dependents, namely Claims 2, 4-5, 7-9 and amended Claims 3 and 6, are patentably distinct from the cited art and respectfully request entry and allowance of these claims.

On page eight of the Office Action, the Examiner rejected Claims 1-11 under 35 U.S.C. § 103(a) as being unpatentable over Awasthi 2001 in view of Sause. For the reasons set forth above, Applicants submit that Claims 1-11 are not anticipated by Awasthi 2001. Combining Awasthi 2001 with Sause, which is non-analogous art that teaches the role of radiotherapy in non-small cell lung cancer, does not overcome the failure of Awasthi 2001 to anticipate each and every element of independent and amended Claim 1 or amended Claim 1 on its whole. For example, Sause does not suggest or teach contacting one or more cells with an antibody to rala binding protein1 wherein the direct contact is cytotoxic to the one or more cells in the absence of an additional agent. In fact, Sause teaches combining treatments such as radiation and chemotherapy and does not teach or suggest using an antibody to rala binding protein1 or using it in the absence of an additional agent. Thus, combining Sause with Awasthi 2001 does not overcome the deficiencies of Awasthi 2001 as described above nor do the combination teach Applicants claimed invention on its whole. With such differences in teachings between Awasthi 2001 and Sause, no person of ordinary skill would have reason to combine such references to provide for Applicants' invention as claimed in amended Claim 1. Moreover, there is no teaching or suggestion in Awasthi 2001 or in Sause to modify or combine references in such a way that would resemble Applicants' invention as claimed in amended Claim 1; nor is there any indication of a reasonable expectation of success if such references were to be combined. Accordingly, Applicants submit that amended Claim 1 and its dependents, namely Claims 2, 4-5, 7-11 and amended Claims 3 and 6, are patentably distinct from the cited art and respectfully request entry and allowance of these claims.

On page nine of the Office Action, the Examiner rejected Claims 19-20 under 35 U.S.C. § 103(a) as being unpatentable over Chen et al. in combination with Awasthi 2001. The Examiner states that Chen et al. teach antibodies immunospecific for polypeptides expressed in

lung cancer pointing to paragraphs [0022] and [0154] as examples. Applicants disagree with the statement, pointing out that in paragraph [0022], Chen et al. teach identifying therapeutic agents targeted to lung cancer specific genes. The lung cancer specific genes (LSGs) are analyzed from a sample (e.g., cells, tissues or bodily fluid) taken from a patient (e.g., paragraphs [0136], [0137], [0140], [0145], as examples). Applicants further point out that in paragraph [0154], Chen et al. teach raising antibodies that specifically bind to LSGs circulating in the body, which is not equivalent to an antibody binding to ralA binding protein1, wherein the antibody is connected to tracer molecule and the tracer molecule is capable of identifying the location of the cell in the absence of an additional agent. Combining Chen et al. with Awasthi 2001 does not overcome the failure of Chen to anticipate each and every element of independent and amended Claim 19 or amended Claim 19 on its whole. Because of the different teachings of Awasthi 2001 and Sause, no person of ordinary skill would have reason to combine such references to provide for Applicants' invention as claimed in amended Claim 19. Moreover, there is no teaching or suggestion in Chen et al., or Awasthi 2001 to modify or combine references in such a way that would resemble Applicants' invention as claimed in amended Claim 19; nor is there any indication of a reasonable expectation of success if such references were to be combined. Accordingly, Applicants submit that amended Claim 19 and its dependent, Claims 20, are patentably distinct from the cited art and respectfully request entry and allowance of these claims. Claim 19 has been amended to include a method of "locating a cell undergoing uncontrolled growth comprising the step of contacting the one or more cells with an antibody to ralA binding protein1, wherein the antibody is connected to a tracer molecule and the tracer molecule is capable of identifying the location of the one or more cells in the absence of an additional agent." [Emphasis shows amended text] No new matter has been introduced with this amendment. Accordingly, entry and allowance of the amendment is respectfully requested.

Conclusion

In light of the amendments, remarks and arguments presented with this Amendment, Applicants respectfully submit that the pending and amended claims are in condition for allowance. Accordingly, favorable consideration for and allowance of such claims are respectfully requested.

A petition with fees for a three-month extension of time is included herewith. No additional fees are believed due with this Amendment. If this is incorrect, the Commissioner is authorized to charge those additional fees, other than the issue fee, that may be required by this paper to Deposit Account No. 07-0153.

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

Dated: January 6, 2006

Respectfully submitted,

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